510 (K) Summary
Revolution™ 45 MHz Rotational IVUS Imaging Catheter

Date Prepared: March 28, 2008

MAY 12 2008

Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Jennifer Motto
Specialist, Regulatory Affairs

Phone number: (916) 231-4509
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Device Name: Revolution™ 45 MHz Rotational IVUS Imaging Catheter

Classification name:	**Class**
• 870.1200 Diagnostic Intravascular catheter	II
• 892.1560 Ultrasonic pulsed echo imaging system	II
• 892.1570 Diagnostic ultrasonic transducer	II

Predicate Device:
The Revolution® 45 MHz Rotational Imaging Catheter is substantially equivalent to the Revolution® 45 MHz Rotational Imaging Catheter cleared under K050995 on 06/20/2005.

Intended Use:

The Revolution® 45 MHz Rotational IVUS Imaging Catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidate for transluminal coronary interventional procedures.

Device Technological Characteristics and Comparison to Predicate Device:

The Revolution® 45 MHz Rotational IVUS Imaging Catheter is substantially equivalent to the Revolution® 45 MHz Rotational Imaging Catheter cleared under K050995 on 06/20/2005. Modifications include implementation of a double seal on the pouch packaging.

The Revolution® 45 MHz Rotational Imaging Catheter uses the same fundamental scientific technologies and has the same intended use as that of the predicate device, Revolution® 45 MHz Rotational Imaging Catheter.

Performance Data:
Applicable testing was performed in accordance with Design Controls including a risk analysis addressing the impact of modifications to the device and components. The test results indicate the subject device is comparable to the predicate device.

Conclusion:
Revolution® 45 MHz Rotational Imaging Catheter has the same *Intended Use* and utilizes the same *fundamental scientific technology* as that of the predicate device, Revolution® 45 MHz Rotational Imaging Catheter cleared under K050995 on 06/20/2005.

Implementation of the double seal to the pouch package does not raise any new questions regarding safety and efficacy. The test results and a declaration of conformity with design controls support a determination of substantial equivalence of the subject device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2008

Volcano Corporation
c/o Ms. Jennifer Motto
Specialist, Regulatory Affairs
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K080891
Trade/Device Name: Revolution 45 MHz Rotational IVUS Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: OBJ
Dated: March 5, 2008
Received: March 6, 2008

Dear Ms. Motto:

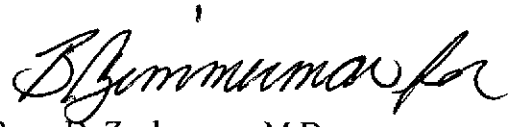
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080891

Device Name: Revolution® 45MHz Rotational Catheter

Indications for Use:

The Revolution catheter is intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080891